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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,146	12/04/2003	Timothy A. Ringeisen	KN P 0146	1356
42016	7590	01/12/2010		
KENSEY NASH CORPORATION 735 PENNSYLVANIA DRIVE EXTON, PA 19341			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			01/12/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/729,146	<b>Applicant(s)</b> RINGEISEN ET AL.	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-26, 28-33, 36-50, 52-69, 71-73, 75-87, 90-93 and 95 is/are pending in the application.
- 4a) Of the above claim(s) 66-69, 71-73, 91 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-26, 28-33, 36-50, 52-65, 75-87, 90, 93 and 95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicants amendments to the claims filed 09/21/2009 have been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 22-26,28-33,36-41,75-77,80-81,84,87, 90, 93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone (US 5,158,574), as evidenced by Tokyo et al. (US 3,616,205), for the reasons set forth in the previous office actions filed 05/09/2008, 12/04/2008 and 06/18/2009.**

**Claims 22-26,28-30,36-38,42-45,47-48,52-65,75-84,87,90,93 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US 2002/0127270), as evidenced by Tokyo et al. (US 3,616,205), for the reasons set forth in the previous office actions filed 05/09/2008, 12/04/2008 and 06/18/2009.**

**Claims 22-26,28-33,36-50,52-65,75-87,90,93 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,158,574), as evidenced by Tokyo et al. (US 3,616,205) in view of Li et al. (US 2002/0127270) and in further**

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**view of Haldimann (US 6,428,576 B1, disclosed previously), for the reasons set forth in the previous office actions filed 05/09/2008, 12/04/2008 and 06/18/2009.**

***Response to Arguments***

Applicant's arguments filed 09/21/2009 have been fully considered but they are not persuasive.

Applicants assert none of the cited references above recite or suggest the use of soluble collagen. Applicants also traverse the examiners reasoning that any collagen can be interpreted as soluble depending upon the conditions used. Applicants further purport that their specification provides guidance for what types of collagens they would interpret as soluble and insoluble such as the specifications reference to acid soluble collagens as soluble and example 1 that gives a specific example of an insoluble collagen. Applicants assert that even if the fibrous collagen of Stone and Li could be solubilized under the right conditions there is no disclosure within either reference on why this would be wanted or that it would function properly in the context of the disclosed inventions.

The examiner notes that applicants have not provided a declaration from the inventor(s) showing that the collagens of Li and Stone are incapable of being solubilized. Furthermore the examiner notes that applicants have not provided a definition for "soluble collagen" within their specification, therefore the term is open to interpretation as to what types of collagen are considered as meeting soluble. As described in the previous office action the examiner does not find the limitation "soluble collagen" to be particularly limiting since it doesn't set forth any conditions in which the

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collagen is solubilized nor is such a term defined within the specification. Thus essentially any collagen could read on soluble collagen, since the conditions used to solubilize the collagen would be limitless (high temperature, use of pepsin, proteolytic enzymes, under acidic conditions ect). Both Stone and Li teach the use of collagen along with other fibers for making the implants, thus applicants have not amended their claims in such a way to preclude either the Stone or Li references. As evidence the examiner relies upon the description within Tokyo, who clearly describes methods to solubilize even so called insoluble collagens. See entire description within. Thus the examiner considers any collagen as being capable of being solubilized depending upon the conditions used.

### ***Conclusion***

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618